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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,361	10/06/2000	Alexander Gaiger	210121.465C2	9832

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

#1C

Office Action Summary	Application No.	Applicant(s)	
	09/684,361	GAIGER ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7,46-51,55,57 and 59-63* is/are pending in the application.

4a) Of the above claim(s) *46,55,61 and 62* is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 47-51* is/are allowed.

6)☒ Claim(s) *6,7,57,59,60,63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/18/2005 has been entered.

2. Claims 1,6,7,47-51,57,59,60,63 are under consideration.

3. Regarding applicants comments about claims 61-62, said claims are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. The invention of claims 61,62 encompasses a species of peptide comprising greater than amino acids 1-249 of WT1, whilst the previously examined species (now claim 57) encompasses peptides comprising SEQ. ID. NO:144 that are less than amino acids 1-249 of WT1. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61,62 were withdrawn from consideration as being directed to a non-elected species in the previous Office action. See 37 CFR 1.142(b) and MPEP § 821.03.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 57,59,60,63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally fled for the peptide recited in claim 57. Regarding applicants previous comments regarding support for said claim,

while Figure 1 discloses full length WT1, there is no disclosure in the specification as originally filed for the particular peptide fragments recited and encompassed by claim 57.

There is no support in the specification as originally fled for the peptide recited in claim 63. Regarding applicants comments regarding support for said claim, while Figure 1 discloses full length WT1, there is no disclosure in the specification as originally filed for the scope of the particular peptide fragments recited and encompassed in claim 63.

There is no support in the specification as originally filed for the scope of the claimed invention (eg. the claimed invention constitutes new matter).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 7 lack antecedent basis in claim 1. Claim 1 is drawn to a peptide that consists of SEQ ID NO:144 and does not encompass fragments of said peptide, whilst claims 6 and 7 encompass fragments of said peptide.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 57,59,60,63 are rejected under 35 U.S.C. 103(a) as obvious over Herlyn et al. (WO 95/29995) in view of Jager et al. (US Patent 6,096,313).
Herlyn et al. teach a peptide comprising SEQ. ID No:144 (eg. see page 19, last paragraph and SEQ. ID No:4 of Herlyn et al., wherein SEQ. ID. No:144 is found in amino acids 1-181 of human WT1), wherein said peptide is immunogenic (eg. it induces antibodies, see page 20). The peptide "consists of no more than amino acids 1-249 of WT1" and does not comprise full length WT1. Herlyn et al. does not teach a composition containing the claimed peptide and GM-CSF. Jager et al. teach use of GM-CSF as an adjuvant and compositions containing GM-CSF and a peptide (see column 6, second paragraph and column 1, first paragraph and claim 1). Jager et al. teach that GM-CSF can enhance the immune response against an antigen (see column 6, second paragraph). GM-CSF enhances a T cell response in a patient (eg. see example 4). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because Herlyn et al. teach the peptides recited in the claims while Jager et al. teach use of GM-CSF as an adjuvant and that GM-CSF can enhance the immune response against an antigen. One of ordinary skill in the art would have been motivated to do the aforementioned because Jager et al. teach that GM-CSF can enhance the immune response against an antigen (column 6, second paragraph). Thus, using said composition, a routineer would have achieve superior results when immunizing animals to produce antibodies as per Herlyn et al.

Regarding applicants comments, Herlyn et al. teach a peptide comprising SEQ. ID No:144 (eg. see page 19, last paragraph wherein SEQ. ID. No:144 is found in amino acids 1-181 of human WT1), wherein said peptide is immunogenic (eg. it induces antibodies, see page 20). The peptide "consists of no more than amino acids 1-249 of WT1". Regarding applicants comments, Jager et al. teach use of GM-CSF as an adjuvant and compositions containing GM-CSF and a peptide (see column 6, second paragraph and column 1, first paragraph and claim 1). Jager et al. teach that GM-CSF

can enhance the immune response against an antigen (see column 6, second paragraph). GM-CSF enhances a T cell response in a patient (eg. see example 4). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because Herlyn et al. teach the peptides recited in the claims while Jager et al. teach use of GM-CSF as an adjuvant and that GM-CSF can enhance the immune response against an antigen. One of ordinary skill in the art would have been motivated to do the aforementioned because Jager et al. teach that GM-CSF can enhance the immune response against an antigen (column 6, second paragraph). Thus, using said composition, a routineer would have achieve superior results when immunizing animals to produce antibodies as per Herlyn et al. In addition, GM-CSF as recited in claim 60 depends from claim 59, which depends from claim 57, so GM-CSF has the functional property of the immune response enhancer recited in claim 57. Regarding motivation to create the claimed invention, Jager et al. teach that GM-CSF can enhance the immune response against an antigen (see column 6, second paragraph) and therefore, using said composition, a routineer would have achieve superior results when immunizing animals to produce antibodies as per Herlyn et al.

The instant rejection renders obvious the claimed composition. The MPEP section 2144 discloses:

RATIONALE DIFFERENT FROM APPLICANT'S IS PERMISSIBLE

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) (discussed below). Although Ex parte Levengood, 28 USPQ2d 1300, 1302 (Bd. Pat. App. & Inter. 1993) states that obviousness cannot be established by combining references "without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done" (emphasis added), reading the quotation in context it is clear that while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

Applicants arguments involve a particular motivation to create the claimed composition, however as per above a different motivation to create the claimed composition is acceptable in a rejection under 35 USC 103. In the instant rejection, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed inventions because Herlyn et al. teach the peptides recited in the claims while Jager et al. teach use of GM-CSF as an adjuvant and that *GM-CSF can enhance the immune response against an antigen*. One of ordinary skill in the art would have been motivated to do the aforementioned because *Jager et al. teach that GM-CSF can enhance the immune response against an antigen* (column 6, second paragraph). *Thus, using said composition, a routineer would have achieve superior results when immunizing animals to produce antibodies as per Herlyn et al.* Regarding motivation to create the claimed invention, Jager et al. teach that GM-CSF can enhance the immune response against an antigen (see column 6, second paragraph) and therefore, using said composition, a routineer would have achieve superior results when immunizing animals to produce antibodies as per Herlyn et al.

10. Claims 1,47-51 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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